II. 510(k) Summary

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JUL 18 2013

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DATE: May 6, 2013

DEVICE INFORMATION

DEVICE NAME:	IC-BAP-DL BioArterial Plus Arterial Blood Flow Enhancement System
Classification Panel:	Cardiovascular and Respiratory Devices
Classification Number:	870.5800
Product Nomenclature:	Compressible Limb Sleeve
Product Code(s):	JOW
Trade/Proprietary Name:	IC-BAP-DL BioArterial Plus Arterial Blood Flow Enhancement System
Common Name:	BAP-DL BioArterial Plus Arterial Blood Flow Intermittent Circulator

DEVICE CLASSIFICATION
Compressible Limb Sleeve Devices are classified as Class II devices, and reviewed by the Division of Cardiovascular and Respiratory Devices.

PREDICATE DEVICE
Model IC-BAP BioArterial Plus Arterial Blood Flow Enhancement System

DEVICE DESCRIPTION

The IC-BAP-DL BioArterial Plus Arterial Blood Flow Enhancement System (IC-BAP-DL, applicant device) is intended for the improvement of blood circulation in the lower extremities to help prevent and reduce complications of poor circulation by increasing arterial blood flow through the application of bilateral or unilateral intermittent compression to the foot and calf.

The device consists of an AC-powered pump, inflatable garments, and interconnection tubing. In operation, the device is attached via the interconnection tubing to sleeves or garments containing discrete inflatable chambers, which are applied externally and bilaterally over the feet and calves. Unique connector fittings on the interconnect tubing prevent accidental and incorrect pump/garment/anatomy combinations or use with garments or sleeves from other manufacturers.

The pump design provides intermittent, rapid impulse pressurization to the chambers. Inflation and deflation cycles are regulated by a two-section valve, turned by the valve motor at three rpm. The pressure is regulated by a digital pressure sensor that turns the air compressor pump on and off using information from the pressure sensor. When the garments are inflated, they compress the blood vessels in the foot and calf, expelling blood from the leg, overcoming blood stasis and promoting circulation.

Pressure is pre-set at the factory to 120 mmHg, and the compressor is capable of no more pressure than 150 mmHg, making the device intrinsically safe. Pressure can be adjusted up or down in increments of 1 mmHg with the UP/DOWN soft key arrows. An LED panel displays the set pressure and display "0" during the deflation cycle.

Foot/calf garments are connected and are available in a range of sizes. The garments contain discrete, interconnected and segmented inflatable chambers, providing a single inflation chamber for the foot and two inflation chambers for the calf. Garments are supplied non-sterile, intended for single patient use, and are intended to be applied over bandages or clean hosiery. Velcro fasteners support garment application. The device is intended for home use, and instructions are provided for the patient to attach the garments and perform therapy after physician prescription and patient orientation and education.

The user interface consists of a soft keypad and UP/DOWN pressure adjustment soft key arrows. All controls and measurement functions are contained in the PCB assembly. When turned on, the timer sends a signal to start the pump and the valve motor. The pump sends air through the 2-section valve, which turns and sends air to the two bilateral output ports, filling first the foot and then the calf garments. As the valve continues to rotate the air is released from all chambers at once and the garments deflate. The cycle repeats three times per minute and default treatment time is one hour, controlled by an internal timer on the PCB.

INDICATIONS FOR USE

The BAP-DL BioArterial Plus Arterial Blood Flow Enhancement System is intended as an adjunct therapy for patients with ischemic disease of the lower extremities, due to one or more of the following causes: • amputations (minor) • angioplasty/stent failure • arteriopathic wounds • graft failure • intermittent claudication • ischemia • night pain • rest pain • small vessel disease • ulcers.

TECHNOLOGICAL CHARACTERISTICS

The manufacturer believes that the technological characteristics of the modified IC-BAP-DL BioArterial Plus Arterial Blood Flow Enhancement System device are substantially similar to those of the predicate IC-BAP BioArterial Plus Arterial Blood Flow Enhancement System. The user interface has been modified from a regulator and analogue pressure gauge in the predicate to a digital pressure sensor and LED display in the applicant device. In place of a manual adjustment knob on the regulator in the predicate device, the pressure can be increased or decreased in increments of 1 mmHg via a soft keypad on the applicant device.

PERFORMANCE DATA

Before being released every device is tested and must meet all performance specifications. In addition to aesthetic acceptance criteria, functional testing includes electrical leakage, pressure adjustment, inflation pressure in each segment, air pressure display accuracy, and inflation/deflation cycle times. The results demonstrate comparable inflation cycle profiles (rise times, inflation pressures, deflation times and cycle times) between the applicant and predicate devices.

STATEMENT OF SUBSTANTIAL EQUIVALENCE

Similarities

Both the applicant and the predicate devices provide continuous intermittent pneumatic pressure bilaterally to the foot and calf using inflatable garments. The applicant and predicate devices have the same intended use and indications for use, both operate within the same clinically-established parameters and both have the same performance specifications. The applicant and predicate devices use the same prescribed inflation pressures, inflation and deflation times and cycle times.

Differences

The applicant device utilizes a digital pressure sensor and LED pressure display while the predicate device utilizes an analogue gauge and needle display. The applicant has soft key up and down arrows to adjust pressure up or down, accessible by pressing an access sequence on the soft keys, while the predicate device has a locking pressure control knob attached to a regulator.

The differences between the predicate and the applicant devices do not impact safety or effectiveness. A table illustrating the similarities and differences is provided below.

Table of Similarities and Differences with the Predicate Device

Parameter	**Predicate K072666** IC-BAP BioArterial Plus Arterial Blood Flow Enhancement System	**Digital** IC-BAP-DL BioArterial Plus Arterial Blood Flow Enhancement System
Intended Use	The IC-BAP System is intended for the improvement of blood circulation in the lower extremities to help prevent and reduce complications of poor circulation, by increasing arterial blood flow through the application of bilateral or unilateral intermittent compression to the foot and calf. The device is intended for home use.	Same
Principal of Operation	Intermittent Pneumatic Compression	Same
Weight	7.5 pounds	7.5 pounds
Dimensions, inches	5 H X 8 W X 12 D	5 H x 8 W x 8 D
# of Segments in garment(s)	1 (foot) and 2 (calf)	Same
Inflation Time, each segment	4 ± 0.5 seconds bilateral	Same
Deflation Time	16 ± 3 seconds	Same
Delay Time between Foot and Calf	1 second ± 0.5 seconds	Same
Cycle Frequency	3 cycles per minute	Same
Recommended Inflation Pressure	120 mmHg	Same
Treatment Durations	60 ± 5 minutes	same
Pressure Adjustment	Locking adjustable knob on regulator	Digital, soft keypad, 1mmHg increments
Pressure Gauge	0-125 mmHg, analog	0 - 150 mmHg, digital
Displayed Pressure Accuracy	± 10 mmHg of sleeve pressure, real time pressure displayed on gauge face	± 10 mmHg of sleeve pressure, pressure set point displayed on LED
Pause time between inflation cycles	None (deflation time is pause time)	Same
Garments Available	Standard, APG-3045-FC S Wide, APG-3045-FC Custom	Same
Fail-safe hose connectors	Yes	Yes
Bilateral Treatment Option	Yes	Yes
Power Requirements	120VAC, 60Hz, 0.5A	Same

CONCLUSION

There is no change in fundamental technology between the IC-BAP-DL BioArterial Plus Arterial Blood Flow Enhancement System and the predicate device. Based upon safety and performance testing, compliance with voluntary standards, and comparison to the predicate devices, the manufacturer believes that the IC-BAP-DL BioArterial Plus Arterial Blood Flow Enhancement System is substantially equivalent to the predicate device, and does not raise any new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 18, 2013

Bio Compression Systems, Inc.
C/O Maureen Garner
P.O. Box 5374
Toms River, NJ 08754

Re: K131327
Trade/Device Name: IC-BAP-DL BioArterial Plus Arterial Blood Flow Enhancement System
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: II
Product Code: JOW
Dated: May 28, 2013
Received: May 29, 2013

Dear Ms. Garner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram Zuckerman, MD
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

I. Indications for Use Statement

510(k) Number: K131327

Device Names: IC-BAP-DL BioArterial Plus Arterial Blood Flow Enhancement System

Indications for Use:

The IC-BAP-DL BioArterial Plus Arterial Blood Flow Enhancement System is intended as an adjunct therapy for patients with ischemic disease of the lower extremities, due to one or more of the following causes:

- Amputations (minor)
- Angioplasty / stent failure
- Arteriopathic wounds
- Graft failure
- Intermittent claudication
- Ischemia
- Night pain
- Rest pain
- Small vessel disease
- Ulcers

Prescription Use (Part 21 CFR 801 Subpart D) X _____ AND/OR Over-The-Counter Use (21 CFR 807 Subpart C) _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)